

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**THE CITY OF HUNTINGTON,
Plaintiff,**

v.

CIVIL ACTION NO. 3:17-01362

**AMERISOURCEBERGEN DRUG
CORPORATION, et al.,
Defendants.**

**CABELL COUNTY COMMISSION,
Plaintiff,**

v.

CIVIL ACTION NO. 3:17-01665

**AMERISOURCEBERGEN DRUG
CORPORATION, et al.,
Defendants.**

PLAINTIFFS' MOTION IN LIMINE TO PRECLUDE ANY REFERENCE TO THE DEA APPROVING OR ENDORSING A PARTICULAR DEFENDANT'S SOM PROGRAM

In an effort to refute Plaintiffs' claim that they failed to maintain effective controls against diversion in violation of the Controlled Substances Act ("CSA") and its implementing regulations, Defendants may try to introduce evidence that the Drug Enforcement Agency ("DEA") approved or endorsed a Defendant's Suspicious Order Monitoring ("SOM") program. Evidence of this nature is inadmissible because it purports to state a conclusion of law—that a Defendant's SOM program was CSA-compliant.

Plaintiffs allege that Defendants violated the CSA and claim that these violations form one of the bases for their public nuisance claim. Defendants have made clear that they will attempt to excuse their compliance failures by asserting that the DEA did not clearly explain their statutory responsibilities or approved or failed to detect their violations of law. Of course, "ignorance of

the law is no defense . . . , whether the law be a statute or a duly promulgated and published regulation.” *U.S. v. Int’l Minerals & Chem. Corp.*, 402 U.S. 558, 563 (1971). Nor can Defendants claim that DEA’s failure to advise them that their programs were deficient – either by design or in practice – constitutes confirmation that their programs were sufficient. As laid out in evidence that has and will be presented, DEA repeatedly explained to Defendants what the CSA required and took numerous enforcement actions against Defendants and other registrants for their failures to comply. Particularly in this context, Defendants cannot, as a matter of fact, claim that the DEA approved their conduct or, as a matter of law, seek to estop Plaintiffs from raising their failures in the present action.

The scope of Defendants’ duties under the CSA and the DEA’s regulations is a pure question of law. *See, e.g., Minnieland Pvt. Day School, Inc. v. Applied Underwriters Captive Risk Assur. Co.*, 867 F.3d 449, 458 (4th Cir. 2017) (“An issue of statutory interpretation is a pure question of law[.]”) (internal quotation marks and citation omitted); *United States v. Moriello*, 980 F.3d 924, 934 (4th Cir. 2020) (“Regulatory interpretation is a question of law.”). Defendants should not be permitted to introduce evidence, including, but not limited to, statements of individual DEA agents regarding the scope of the CSA that contradict the Act itself and the DEA’s regulations. *See Allstate Ins. Co. v. Rochkind*, 381 F. Supp. 3d 488, 510 (D. Md. 2019) (“But, testimony that states a legal conclusion is not admissible.”); *see also United Staes v. McIver*, 470 F.3d 550, 561-62 (4th Cir. 2006) (“However, opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.”).

Moreover, the statements of an individual DEA employee purporting to “approve” or “endorse” a particular Defendant’s SOM program are irrelevant to the ultimate issue of whether that Defendant complied with the CSA’s SOM requirements. The DEA has repeatedly told “every

entity in the United States registered with the [DEA] to manufacture or distribute controlled substances” that the “regulation clearly places the responsibility on the registrant to design and operate [a SOM] system[,]” and thus, “DEA does not approve or otherwise endorse any specific system for reporting suspicious orders.” Ex. A (DEA December 12, 2007 letter) at p.1; Ex. B (DEA June 12, 2012 letter) at p.1 (same). Moreover, in December 2007, DEA specifically informed all registrants that any “[p]ast communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.” Ex. A at p.1.

Thus, any statements to the contrary cannot be construed as official “approvals” or “endorsements” by the DEA. Moreover, a DEA employee cannot individually authorize that which the law does not sanction or permit. *See Office of Personnel Mgmt. v. Richmond*, 496 U.S. 414, 420 (1990) (“[T]he United States is neither bound nor estopped by acts of its officers or agents in entering into an arrangement or agreement to do or cause to be done what the law does not sanction or permit.”) (internal quotation marks and citation omitted).¹

In the MDL, Judge Polster denied the CT1 Plaintiffs’ pre-trial motion in limine for the same type of relief Plaintiffs seek here, but did so without prejudice and ruled further that “any statements by DEA agents that contradict the requirements of the Controlled Substances Act or otherwise misstate the law will be subject to exclusion.” *Nunc Pro Tunc* Evidentiary Order (MDL

¹ See also *Wilber Nat. Bank of Oneonta, N.Y. v. U.S.*, 294 U.S. 120, 123-24 (1935) (same; “Also, those dealing with an agent of the United States must be held to have had notice of the limitation of his authority.”); *Niewiadomski v. U.S.*, 159 F.2d 683, 688 (6th Cir. 1947) (same; “Government officers may not waive the provisions of the National Service Life Insurance Act.”); *Washington Tour Guides Ass’n v. Natl. Park Serv.*, 808 F. Supp. 877, 881-82 (D.D.C. 1992) (“The National Park Service is not bound by oral agreements made by its officers when those agreements contravene clear regulatory language.”); *U.S. v. City of Menominee, Mich.*, 727 F. Supp. 1110, 1121 (W.D. Mich. 1989) (“[R]egardless of any ‘admissions’ made by USEPA officials, ‘generally speaking public officers have no power or authority to waive the enforcement of the law on behalf of the public.’ ”) (citation omitted); *U.S. v. Articles of Drug . . . Hormonin*, 498 F. Supp. 424, 435-36 (D.N.J. 1980) (noting that this “general rule has been applied several times in the context of statements and representations made by agents of the FDA”), *aff’d sub nom. App. of Carnrick Lab’, Inc.*, 672 F.2d 902 (3d Cir. 1981), and *aff’d sub nom. U.S. v. Articles of Drug*, 672 F.2d 904 (3d Cir. 1981).

ECF No. 3058) at 22-23 and n.46. Given that this Court already has ruled that testimony on “the content of the law” and “how the law applies to defendants” is “not helpful because the court is capable of understanding the law at issue here[,]” Memo. Op. and Order excluding expert opinions of James Geldhof (ECF No. 1269) at 4-5, the Court should exclude this evidence altogether.

Defendants may try to argue that this evidence is relevant to an equitable estoppel defense to their CSA violations. It is not. In West Virginia,

‘The general rule governing the doctrine of equitable estoppel is that in order to constitute equitable estoppel or estoppel in pais there must exist a false representation or a concealment of material facts; it must have been made with knowledge, actual or constructive of the facts; the party to whom it was made must have been without knowledge or the means of knowledge of the real facts; it must have been made with the intention that it should be acted on; and the party to whom it was made must have relied on or acted on it to his prejudice.’

Ryan v. Rickman, 213 W. Va. 646, 649, 584 S.E.2d 502, 505 (2003) (*per curiam*) (quoting *Stuart v. Lake Wash. Realty Corp.*, 141 W. Va. 627, 92 S.E.2d 891, Syl. pt. 6 (1956)).

Preliminarily, even if individual DEA agents made misrepresentations to certain Defendants, neither the DEA nor the federal government is the party against whom estoppel would be asserted in this case. Thus, no statements of individual DEA agents can be used as the basis for an estoppel argument against the claims of Plaintiffs here. *See Niewiadomski*, 159 F.2d at 688 (“In order to create estoppel, it is necessary that misrepresentation be made by the party sought to be estopped.”).

Moreover, “[i]t is ‘well settled that the Government may not be estopped on the same terms as any other litigant.’” *Dole v. Odd Fellows Home Endowment Bd.*, 912 F.2d 689, 695 (4th Cir. 1990) (quoting *Heckler v. Community Health Servs.*, 467 U.S. 51, 60 (1984)). “When the Government is unable to enforce the law because the conduct of its agents has given rise to an estoppel, the interest of the citizenry as a whole in obedience to the rule of law is undermined.”

Heckler, 467 U.S. at 60. Estoppel may not be invoked “as a means of successfully avoiding the requirements of legislation enacted for the protection of the public interest.” *P. Shrimp Co. v. U.S. Dept. of Transp.*, 375 F. Supp. 1036, 1042 (W.D. Wash. 1974) (“An administrative agency charged with protecting the public interest, is not precluded from taking appropriate action nor can the principles of equitable estoppel be applied to deprive the public of a statute’s protection because of mistaken action or lack of action on the part of public officials.”); *see also Washington Tour Guides*, 808 F. Supp. at 882 (“Simply put, the government may not be estopped from enforcing the law, even following an extended period of no enforcement or underenforcement.”).²

Thus, a “party attempting to estop the government bears a very heavy burden in sustaining its argument.” *Michigan Exp., Inc. v. U.S.*, 374 F.3d 424, 427 (6th Cir. 2004) (internal quotation marks and citations omitted). In addition to proving the ordinary elements of estoppel,

[A] party seeking to equitably estop the government bears the burden of proving two additional elements in order to succeed. These are (1) that the party asserting estoppel must establish affirmative misconduct going beyond mere negligence, and (2) that not applying estoppel would result in a serious injustice, and that the public will not be unduly burdened by the imposition of estoppel.

United States v. Lancaster, 898 F. Supp. 320, 323 (E.D.N.C. 1995).³

² See also *U.S. v. 789 Cases, More or Less, of Latex Surgeons' Gloves, an Article of Device*, 799 F. Supp. 1275, 1297 (D.P.R. 1992) (“It is . . . clear that one cannot invoke estoppel to avoid the requirements of legislation, such as the [Federal Food, Drug, and Cosmetic] Act, which was enacted to protect the public from products that do not comply with the law. . . . Claimant is, in effect, asking this Court to enjoin the FDA from enforcing the law. It is beyond dispute that the government may not be enjoined from enforcing the Act; such relief would merely permit illegal conduct to continue to the detriment of the public.”); *Hormonin*, 498 F. Supp. at 435 (“I have serious reservations as to whether equitable estoppel could ever be invoked to prevent enforcement of the policy of the [Federal Food, Drug, and Cosmetic] Act, i.e., the protection of the public health and safety.”).

³ See also *Abercrombie & Fitch Stores, Inc. v. Am. Com. Const., Inc.*, 2:08-CV-925, 2010 WL 1640883, at *3 (S.D. Ohio Apr. 22, 2010) (“Estoppel does not apply where ‘[t]he government was not attempting to trick’ the party asserting estoppel, but was rather ‘attempting, in good-faith, to advise [the party] as to its intended course of action based on the facts that it knew,’ and not acting with malicious intent.”) (quoting *Michigan Exp.*, 374 F.3d at 428); *Green v. U.S.*, 8 F. Supp. 2d 983, 994-95 (W.D. Mich. 1998) (“The Greens argue that the affirmative misconduct requirement is satisfied through the statements made by Rosenquist, Hare, and other Defendants that the Greens were first on the list to have their loan funded. At most, the statements were made based upon an erroneous application of FSA regulations, and constitute no more than mere negligence. Such statements do not rise to the level of affirmative misconduct required for an estoppel claim against the government.”) (internal citation omitted); *Highland Park Patient Collective, Inc. v. U.S. Dept of J.*, CV1209958RGKFFMX, 2013 WL 12142958, at *4 (C.D.

Additionally, even assuming, *arguendo*, that Defendants had evidence of affirmative misconduct by an individual DEA agent, they must still satisfy the other estoppel elements. They cannot do so. The “party claiming the estoppel must have relied on its adversary’s conduct in such a manner as to change his position for the worse[,] and that reliance must have been reasonable in that the party claiming the estoppel did not know nor should it have known that its adversary’s conduct was misleading.” *Heckler*, 467 U.S. at 59 (internal quotation marks and citation omitted).⁴

Defendants could not have reasonably relied on any statements by individual DEA agents that contradicted the requirements set forth in the CSA and DEA regulations.⁵ “[T]hose who deal with the Government are expected to know the law and may not rely on the conduct of Government agents contrary to law.” *Heckler*, 467 U.S. at 63.⁶ Thus, as registrants, Defendants were obligated to familiarize themselves with the legal requirements of the CSA. Cf. *Heckler*, 467 U.S. at 64 (“As a participant in the Medicare program, respondent had a duty to familiarize itself with the legal requirements for cost reimbursement.”). Moreover, as noted above (*supra* at pp. 2-3), Defendants knew that the DEA had expressly disclaimed the idea that it ever “approved” or “endorsed” any

Cal. Mar. 20, 2013) (“Plaintiff fails to identify any ‘affirmative misconduct’ on the part of a government official, but merely points to government memoranda and unofficial statements that induced Plaintiff to believe that the CSA would not be enforced against it. These facts are insufficient to demonstrate affirmative misconduct. Accordingly, Plaintiff’s estoppel claim fails.”) (internal citation omitted).

⁴ See also *id.* at 59 n.10 (“The truth concerning these material facts must be unknown to the other party claiming the benefit of the estoppel, not only at the time of the conduct which amounts to a representation or concealment, but also at the time when that conduct is acted upon by him. If, at the time when he acted, such party had knowledge of the truth, or had the means by which with reasonable diligence he could acquire the knowledge so that it would be negligence on his part to remain ignorant by not using those means, he cannot claim to have been misled by relying upon the representation or concealment.’ ”) (citation omitted).

⁵ This is particularly true with respect to any oral statements made by individual DEA agents. See *Heckler*, 467 U.S. at 65 (“The necessity for ensuring that governmental agents stay within the lawful scope of their authority, and that those who seek public funds act with scrupulous exactitude, argues strongly for the conclusion that an estoppel cannot be erected on the basis of the oral advice that underlay respondent’s cost reports. That is especially true when a complex program such as Medicare is involved, in which the need for written records is manifest.”).

⁶ See also *Wilber*, 294 U.S. at 124 (“The statutes and regulations which govern the War Risk Insurance Bureau we must assume are known by those who deal with it.”).

particular SOM programs. *Cf. Hormonin*, 498 F. Supp. at 436-37 (rejecting defendant's equitable estoppel defense because, *inter alia*, FDA's publication of a notice in the Federal Register, under which all opinions previously given by the FDA to the effect that an article was not a "new drug" were revoked, plainly operated as a revocation of a prior opinion letter which stated that the drug would not require clearance under the "new drug" procedure with adequate labeling).

Defendants also may try to argue that this evidence is relevant to the issue of intent or knowledge under the CSA, 21 U.S.C. §§ 841 and/or 843. Section 841 provides that "[e]xcept as authorized by [Subchapter I of the CSA], it shall be unlawful for any person knowingly or intentionally . . . to manufacture, distribute, or dispense . . . a controlled substance." 21 U.S.C. § 841(a). Section 843 makes it unlawful for registrants to "knowingly or intentionally . . . furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II[.]" 21 U.S.C. § 843(a)(4). Plaintiffs anticipate that Defendants will claim that they could not have "knowingly and intentionally" violated the CSA because individual DEA agents purportedly told them their SOM programs were compliant. This argument is without merit.

The Supreme Court has stated that, "unless the text of the statute dictates a different result, the term 'knowingly' merely requires proof of knowledge of the facts that constitute the offense[;]" it is not necessary to prove that the defendant knew its conduct was unlawful. *Bryan v. U.S.*, 524 U.S. 184, 192-93 (1998); *see also U.S. v. Fuller*, 162 F.3d 256, 260 (4th Cir. 1998) ("To act 'knowingly' is to act with 'knowledge of the facts that constitute the offense' but not necessarily with knowledge that the facts amount to *illegal* conduct, unless the statute indicates otherwise.") (quoting *Bryan*, 524 U.S. at 192-93) (emphasis in original). Similarly, "to commit an act intentionally is to do so deliberately and not by accident." *Fuller*, 162 F.3d at 260; *see also Memo*.

Op. and Order denying summary judgment on “fault” element of public nuisance (ECF No. 1294) at 5-6 (rejecting Defendants’ argument that intentional wrongdoing requires intent to cause harm). Nothing in the text of §§ 841 and/or 843 indicates that Congress meant to punish only those defendants who actually intended to violate the statute or knew their conduct was illegal.⁷

Accordingly, evidence of a Defendant’s good-faith belief that its conduct is lawful is irrelevant and properly excluded at trial. *See, e.g., U.S. v. Barnes*, 677 Fed. Appx. 271, 278 (6th Cir. Jan. 26, 2017) (“Under the Federal Rules of Evidence, a party is not entitled to present evidence at trial that is not relevant. Relevancy determinations are within the district court’s discretion, and evidence that neither negates an element of the crime charged nor establishes a defense is not relevant. Because the manufacture of marijuana is a general-intent crime, and ignorance of the law is not a defense, evidence that Barnes believed he could manufacture large quantities of marijuana in his home for the ONAC, pursuant to a RFRA exemption, is irrelevant.”) (internal citations omitted).⁸

⁷ *See, e.g., Fuller*, 162 F.3d at 260 (“[I]t is not a requirement of 21 U.S.C. § 841(a) that the defendant have specifically intended to violate the statute in order to be found guilty.”; “[N]othing in the text of 21 U.S.C. § 841(a) indicates that Congress meant to punish only those defendants who actually intended to violate the statute[.]”); *U.S. v. Tobin*, 676 F.3d 1264, 1279–80 (11th Cir. 2012) (“The District Court’s conclusion that the mens rea under Section 841(a)(1) is knowledge rather than willfulness is correct. . . . The language of the statute does not refer, in any way, to willfulness, and as a consequence, we have said that the government only needs to prove that the defendant acted knowingly.”); *U.S. v. Ansaldi*, 372 F.3d 118, 128 (2d Cir. 2004) (“It is unlawful for an individual ‘knowingly or intentionally—(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance.’ 21 U.S.C. § 841(a)(1). Knowledge of, or intent to violate, the law is simply not an element of this offense.”); *Scarmazzo*, 554 F. Supp. 2d at 1109 (“It is not an element of § 841 that Defendant intended to violate a statute.”); *U.S. v. Hoyt*, 2:14CR00001, 2014 WL 5023093, at *7 (W.D. Va. Oct. 8, 2014).

⁸ *See also Tobin*, 676 F.3d at 1280 (“[F]or the distribution counts, the District Court correctly granted the government’s motion in limine to exclude evidence that the defendant subjectively believed that they were not committing the offenses. As the District Court explained, because the mens rea under Section 841(a)(1) consists of knowledge rather than willfulness, any evidence that the defendants had a sincere belief that their distribution of controlled substances was in conformity with the law would be ‘irrelevant’ to the distribution counts and thus inadmissible in that respect.”); *Hoyt*, 2014 WL 5023093, at *6-7 (granting government’s motion “to preclude the defendants from arguing or introducing any evidence showing that they did not know . . . that it was illegal to distribute [controlled substance analogues]”; “[T]here is no statutory requirement in the CSAEA that the defendants realize that their actions were illegal. Therefore, any arguments or evidence presented by the defendants that they did not know that these substances were illegal would be tantamount to an ignorance-of-the-law defense, which is not a valid defense to the charges the defendants face.”).

In sum, any statements purporting to “approve” or “endorse” a Defendant’s SOM program are not relevant to any issue in this case. They are not probative of the scope of Defendants’ duties under the CSA, of whether any Defendant violated those duties, nor of whether such violations were knowing or intentional. The Court therefore should exclude this evidence.

CONCLUSION

For all of the reasons set forth, the Court should exclude any reference to the DEA approving or endorsing a particular Defendant’s SOM program.

Dated: May 14, 2021

Respectfully submitted,

THE CITY OF HUNTINGTON

/s/ Anne McGinness Kearse

Anne McGinness Kearse (WVSB No 12547)

Joseph F. Rice

MOTLEY RICE LLC

28 Bridgeside Blvd.

Mount Pleasant, SC 29464

Tel: 843-216-9000

Fax: 843-216-9450

akearse@motleyrice.com

jrice@motleyrice.com

Linda Singer

David I. Ackerman

MOTLEY RICE LLC

401 9th Street NW, Suite 1001

Washington, DC 20004

Tel: 202-232-5504

Fax: 202-386-9622

lsinger@motleyrice.com

dackerman@motleyrice.com

Charles R. “Rusty” Webb (WVSB No. 4782)

The Webb Law Centre, PLLC

716 Lee Street, East

Charleston, West Virginia 25301

Telephone: (304) 344-9322

Facsimile: (304) 344-1157

rusty@rustywebb.com

CABELL COUNTY COMMISSION

/s/ Paul T. Farrell Jr.

Paul T. Farrell, Jr. (WVSB Bar No. 7443)

FARRELL & FULLER LLC

1311 Ponce de Leon Ave., Suite 202

San Juan, Puerto Rico 00907

Mobile: 304-654-8281

paul@farrellfuller.com

/s/ Anthony J. Majestro

Anthony J. Majestro (WVSB No. 5165)

POWELL & MAJESTRO, PLLC

405 Capitol Street, Suite P-1200

Charleston, WV 25301

304-346-2889 / 304-346-2895 (f)

amajestro@powellmajestro.com

Michael A. Woelfel (WVSB No. 4106)

WOELFEL AND WOELFEL, LLP

801 Eighth Street

Huntington, West Virginia 25701

Tel. 304.522.6249

Fax. 304.522.9282

mikewoelfel3@gmail.com

CERTIFICATE OF SERVICE

I certify that on May 14, 2021, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ *Anthony J. Majestro*